

Patent

Our Docket: 5026C

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Li et al.	) Art Unit: 1633 )
Serial No.: 10/632,302	) Examiner: Robert M. Kelly
Filed: August 1, 2003	) )
For: Genetic modification of the lung as portal for gene delivery	) )
Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450	

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST-CLASS MAIL IN AN ENVELOPE ADDRESSED TO: COMMISSIONER FOR PATENTS, P.O. BOX 1450,

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Signature of person mailing correspondence

### INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 C.F.R. § 1.56, the references listed on the attached Form PTO-1449 are being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application.

In re: Li et al. USSN: 10/632,302 Filed: August 1, 2003 Page 2

# I. Timing of the Information Disclosure Statement:

This Information Disclosure Statement is filed:

Before the mailing date of a first Office Action on the merits. In the event, however, that an Office Action has crossed in the mail with this information Disclosure Statement, the Commissioner is hereby authorized to charge Deposit Account No. 07-1074 for any fees required pursuant to 37 C.F.R. § § 1.17(p) or 1.17(i)(1).

#### II. Copies of the Cited Items:

□ Copies of all of the items listed on the attached Form PTO-1449 are enclosed.

#### III. Concise Explanation of Relevance:

Citation of the above documents shall not be construed as:

- 1. an admission that the documents are necessarily prior art with respect to the instant invention;
- 2. a representation that a search has been made, other than as described above; or
- an admission that the information cited herein is, or is considered to be, material to patentability as defined in § 1.56(b).

It is respectfully requested that the Examiner indicate consideration of the cited references by returning a copy of the attached form PTO 1449 with initials or other appropriate marks. The Commissioner is hereby authorized to charge Deposit Account No. **07-1074** for any additional fees required in connection with the filing of this Information Disclosure Statement.

Respectfully submitted

/Date

Jennifer D. Tousignant

Agent for Applicants Registration No. 54,498

Telephone: (508) 270-2499

Facsimile: (508) 872-5415

GENZYME CORPORATION
15 Pleasant Street Connector
P.O. Box 9322
Framingham, Massachusetts 01701-9322

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Systematics for form 1449A/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known				
Application Number	10/632,302			
Filing Date	August 1, 2003			
First Named Inventor	Li, Chester			
Art Unit	1633			
Examiner Name	Robert M. Kelly			
Attorney Docket Number	5026CON			

U.S. PATENT DOCUMENTS					
Examiner Initials *	Cite No.1	Document Number  Number - Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1	US-5,236,838	08/17/1993	Genzyme Corporation	
	. 2	US- 5,686,240	11/11/1997	Mount Sinai School of Medicine	
<del>,</del>	3	US- 5,811,406	09/22/1998	Regents of University of California	
	4	US- 5,879,680	03/09/1999	US of A, Dept of Health and Human Services	
	5	US- 5,780,014	07/14/1998	Inhale Therapeutic Systems	
	6	US- 6,066,626	05/23/2000	Genzyme Corporation	
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		FOREIGN PA	TENT DOCU	MENTS		
Examiner	Cite	Foreign Patent Document	Publication	Name of Patentee or	Pages, Columns, Lines, Where Relevant	
Initials* No.4	Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> ( <i>if known</i> )	Date MM-DD-YYYY	. Applicant of Cited Document	Passages or Relevant Figures Appear	T <sup>6</sup>	
	7	WO 96/40964	12-19- 1996	Inex Pharmaceutical Corp.		
	8	WO 97/17063	5-15-1997	Microbiological Research Authority		
	9	WO 97/19177	05-29- 1997	Women's and Children's Hospital		
	10	WO 00/33886	06-15- 2000	Genzyme Corporation		

Examiner Signature	Date Considered	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. Applicant is to place a check mark here if English language

Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete,

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Substitute for form 1449B/PTO		Complete if Known			
INFORMATION DISCLOSURE				Application Number	10/632,302
				Filing Date	August 1, 2003
(Use as many sheets as necessary)		First Named Inventor	Li, Chester		
		Art Unit	1633		
		Examiner Name	Robert M. Kelly		
Sheet	2	of	2	Attorney Docket Number	5026CON

		NON PATENT LITERATURE DOCUMENTS	<del></del> -			
Examiner Initials *						
	11	ARMENTANO, D. et al., "Effect of the E4 Region on the Persistence of Transgene Expression from Adenovirus Vectors", Journal of Virology, March 1997, 71(3):2408-2416				
	12	McDONALD, R.J. et al., "Safety of Airway Gene Transfer with Ad2/CFTR2:Aerosol Administration in the Nonhuman Primate", Human Gene Therapy, March 1, 1997, 8:411-422				
	13	KAPLAN, J.M. et al., "Potentiation of Gene Transfer to the Mouse Lung by Complexes of Adenovirus Vector and Polycations Improves Therapeutic Potential", Human Gene Therapy, July 1, 1998, 9:1469-1479	,			
	14	ZIEGLER, R.J. et al., "Correction of Enzymatic and Lysosomal Storage Defects in Fabry Mice by Adenovirus-Mediated Gene Transfer", Human Gene Therapy, July 1, 1999, 10:1667-1682				
<del></del>	15	POENARU, Livia, "Particularities of lysosomal storage diseases gene therapy", Gene Therapy, 1996, 3:1039-1041				
	16	BEERS, M.H. and BERKOW, R., The Merck Manual of Diagnosis and Therapy, 17 <sup>th</sup> Edition, 1999, pp. 214-215, 2338 and 2408				
· .						

Examiner	Date	
Signature	Considered	1,

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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